

Enforcement Response Policy for TSCA Section 4 Test Rules
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MEMORANDUM

SUBJECT: Enforcement Response Policy
for TSCA Section 4 Test Rules

FROM: A. E. Conroy II, Director
Office of Compliance Monitoring (EN-342)

TO: Addressees

Attached is the final Enforcement Response Policy (ERP) for TSCA Section 4 Test Rules. This ERP addresses test rules only. A separate ERP was issued by the Office of Compliance Monitoring (OCM) on April 9, 1985 to address violations of the TSCA Section 4 Good Laboratory Practices rule which appears at 40 CFR Part 792. The interim final rule for test rules appears at 50 FR 20652 (May 17, 1985) and amends 40 CFR Part 790 which was published in the Federal Register on October 10, 1984 (49 FR 39774).

Thank you for reviewing and commenting on the draft policy. The comments and responses are attached for your information. If you have any questions concerning the ERP, please call Richard Green of my staff at (FTS) 382-5567.

Attachments

COMMENTS ON THE DRAFT TSCA SECTION 4 ENFORCEMENT RESPONSE
POLICY

COMMENT 1 - One commenter raised the point that under continuing Violations, single batches lasting more than one day should not be a single day violation if a continuous batch operation is involved.

RESPONSE - OCM agrees with this and the final ERP has been modified to reflect this change.

COMMENT 2 - One commenter questioned if a single batch is manufactured or processed in more than one day, why is each batch calculated as one day in violation?

RESPONSE - OCM considers non-continuous batch operations a single event warranting only a single day penalty assessment even if the batch requires more than one calendar day to produce. For example, this would include a batch requiring 26 hours to produce which starts at 11:00PM on day 1 and lasts until 1:00AM on day 3.

COMMENT 3 - Two commenters suggested that the Overview be revised slightly so that it more accurately describes the conditions which trigger a TSCA Section 4 test rule.

RESPONSE - Noted and incorporated into the final ERP.

COMMENT 4 - One commenter suggested that OCM should include intentional (I. e., willful) delays in the list of acts and omissions warranting criminal sanctions.

RESPONSE - The draft ERP discusses intentional (I. e., willful) violations in a broad fashion because it is a function under the jurisdiction of the Office of Enforcement and Compliance Monitoring (OECM). OCM refers potential criminal cases it has identified to OECM for action. The purpose of this ERP is not to describe in detail criminal sanctions. Rather, it is to provide guidance for the assessment of administrative civil penalties. Intentional delays may be considered criminal on a case-by-case basis, but it will be OECM's responsibility to make such a determination.

COMMENT 5 - One commenter suggested that OCM should define under the "Extent" category what the time periods include.

RESPONSE - A note has been added to the final ERP which defines these time periods as the time spent in the laboratory exclusive of the time spent to analyze data and write reports.

COMMENT 6 - One commenter questioned why falsification is included under civil penalties when it is included under criminal sanctions.

RESPONSE - Falsification requires a case-by-case determination as to whether it warrants criminal or civil action or both. TSCA Section 16(b) states that "Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of any civil penalty...be subject" to criminal sanctions.

COMMENT 7 - Does "Failure to test" under "Circumstances" depend on the willfulness or other reasons for the failure?

RESPONSE - Failure to test may generally be due to willfulness. However, this does not rule out other justifiable reasons.

COMMENT 8 - One commenter suggested that a range of penalties be included for "Failure to adhere to test standards" due to the type of failure occurring.

RESPONSE - The "Circumstances" section has been modified to include three ranges for this violation depending on whether EPA's ability to evaluate the substance is impaired in a serious, important but less than critical, or minor way.

COMMENT 9 - One commenter recommended adding "Failure to seek modifications before change" to "Failure to adhere to test standards".

RESPONSE - OCM agrees with this and it has been added to the "Circumstances" section under levels 1, 3, and 5.

COMMENT 10 - OTS indicated that failure to submit a study plan to EPA by 30 days after the required date may be more serious than indicated because of interference with the audit program. The commenter suggested raising the level from 4 to level 3.

RESPONSE - OCM agrees with OTS that this is comparable to other level 3 violations and has included this change in the final ERP.

COMMENT 11 - OTS stated that the failure to initiate a study by 30 days after the approved date should not be a level 3 violation if the final report is received on time and is accepted by EPA. Recommend downgrading to level 5.

RESPONSE - OCM agrees with OTS and has included this change in the final ERP. However, studies initiated late resulting in late final reports

shall be dealt with as late final reports or late study submissions.

-3-

COMMENT 12 - OTS indicated that there should be some provision to discourage repeated (3 or more times) requests for delays.

RESPONSE - Since this is not a violation of the TSCA Section 790, it will not be addressed in this ERP. However, OCM feels that OTS has the authority under Section 790.35 to deny a request for modification of the schedule if it is not justified. A non-approved modification to the schedule would then be a violation subject to enforcement action.

COMMENT 13 - Several commenters questioned why the calculation of the number of days for a continuing violation is based on the number of days of manufacture or processing. If a manufacturer or processor does not manufacture or process during the violative period, which is very possible for some violations of TSCA Section 4 test rules, would this mean there is no violation or penalty?

RESPONSE - This method of calculation was chosen as a means to assure that companies which manufacture or process numerous days receive higher penalties than companies which manufacture or process fewer days. If a company 1) manufactures or processes after the effective date of the test rule, 2) does not comply with the rule, and 3) subsequently ceases the manufacture or processing; they have violated the test rule and will be assessed a penalty based on the number of days they manufactured or processed. If the company ceases the activity until the end of the reimbursement period, the penalty will not increase.

COMMENT 14 - One commenter suggested that OCM should delete the second paragraph under "Multiple Violations" which excludes failure to submit study plans. By deleting the paragraph, study plans would be included in multiple violations because they may be submitted at separate times under the same test rule.

RESPONSE - The paragraph in question has been modified so as to exclude study plans from multiple violations if the total number of study plans required under one test rule are submitted at the same time by one company or consortium.

COMMENT 15 - Two commenters felt that the penalty adjustment of 50% for combined voluntary and immediate voluntary disclosure of violations was excessive and should be reduced. Another commenter felt that the adjustment was insufficient because it did not provide enough incentive

for companies to come forth voluntarily.

RESPONSE - The 50% reduction parallels the TSCA Section 5 penalty policy supplement issued on January 9, 1985 for voluntary and immediate voluntary disclosure of violations. Hence, we are establishing a uniform structure under TSCA for dealing with these situations.

-4-

COMMENT 16 - One commenter recommended that the "Extent" section include study complexity and potential to identify human and environmental risks as added factors.

RESPONSE - The breakdown of significance by duration of the study under the "Extent" section takes into consideration the study complexity. Using a general rule, as the length of the study increases so does its complexity. Secondly, the "Circumstances" section takes into consideration the degree of impairment on the Agency's ability to evaluate risks. Hence, the "Extent" section will remain unchanged.

COMMENT 17 - One commenter suggested that the "Gains from Noncompliance" be more precisely defined.

RESPONSE - The "Gains from Noncompliance" section will not be defined more precisely in this ERP. However, OCM shall look more closely at this section and provide any necessary modifications at a later date.

COMMENT 18 - One commenter noted that Level 2 of the "Circumstances" section is omitted.

RESPONSE - Level 2 of the "Circumstances" section has been intentionally omitted. The original TSCA Penalty Policy published in the Federal Register on September 10, 1980 provides six categories under the "Circumstances" section as a guideline for the development of future TSCA penalty policies. In this policy, no violations of TSCA Section 4 test rules appeared to clearly fall into level 2. Hence, only five levels are included in this ERP.

COMMENT 19 - One commenter stated "that small manufacturing companies with small staffs face a heavier financial burden in penalties to comply with tardiness or incomplete testing than larger companies who have less of an excuse in manpower or funds. Recommend that either the company's staff size be a mitigating factor or that we change our timeliness of reporting to either a lower level of circumstances or grant more time for the circumstance for all companies."

RESPONSE - 40 CFR 790.35 (the procedural rule) provides all companies with the opportunity to seek justifiable modifications to the schedules. Also, Congress provided for small business exemptions in specific section of TSCA.

-5-

COMMENT 20 - One commenter stated that for the purposes of negotiations after a complaint is issued, it would be useful to reserve part of the 50% adjustment for voluntary disclosure.

RESPONSE - OCM agrees with this comment. The paragraph for Adjustment Factors for Voluntary Disclosure states that all reductions in the gravity based penalty other than the first 25% reduction for voluntary disclosure should be made after the complaint is issued.

ENFORCEMENT RESPONSE POLICY

FOR TEST RULES UNDER

SECTION 4 OF THE

TOXIC SUBSTANCES CONTROL ACT

OFFICE OF COMPLIANCE MONITORING

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ENFORCEMENT RESPONSE POLICY FOR TSCA SECTION 4 TEST RULES

	PAGE
<hr/> OVERVIEW <hr/>	1.
<hr/> APPLICABILITY <hr/>	1.
<hr/> LEVELS OF ACTION <hr/>	1-2.
NOTICES OF NONCOMPLIANCE	1-2.
CIVIL PENALTIES	2.
CRIMINAL SANCTIONS	2.
<hr/> ASSESSMENT OF CIVIL PENALTIES <hr/>	2-7.
GRAVITY BASED PENALTY MATRIX	3.
NATURE	3.
EXTENT	3.
CIRCUMSTANCES	4-5.
CONTINUING VIOLATIONS	5-6.
MULTIPLE VIOLATIONS	6-7.
ADJUSTMENT FACTORS	7.
Voluntary Disclosure	7.

Immediate Voluntary Disclosure	7.
Gains from Noncompliance	7.

APPENDIX - Chart for Penalty Calculations

TSCA SECTION 4 TEST RULES

ENFORCEMENT RESPONSE POLICY

OVERVIEW

Under section 4 of the Toxic Substances Control Act (TSCA), EPA is authorized to promulgate rules which require that selected chemical substances or mixtures be tested to evaluate concerns for specific effects on human health or the environment. The Agency shall promulgate a TSCA Section 4 test rule if it finds that a) the substance or mixture may present an unreasonable risk of injury to health or the environment or b) it enters or may enter into the environment in substantial quantities or it poses or may pose significant human exposure. EPA must also find that there are insufficient data and experience to reasonably determine health and environmental effects and that testing is necessary to develop such data.

APPLICABILITY

Specific Chemical Substance and Mixture Test Rules (40 CFR 799) apply to persons who manufacture or intend to manufacture (including import) and/or persons who process or intend to process specific chemical substances or mixtures identified in 40 CFR 799, Subpart B during the period commencing with the effective date of the specific test rule until the end of the reimbursement period. Each set of testing requirements in Subpart B specifies whether those requirements apply to manufacturers, processors, or both. This policy does not address violations which are associated with good laboratory practice (GLP) requirements for these specific test rules. However, the Office of Compliance Monitoring (OCM) issued a separate enforcement response

policy on April 9, 1985 to address GLP violations.

LEVELS OF ACTION

NOTICES OF NONCOMPLIANCE (NON)

All notices of noncompliance will involve minor violations of the TSCA Section 4 test rule which are not considered substantive.

An example would be the submission of a timely letter of intent to conduct testing or a timely request for exemption from testing for each required test but failure to provide all the required information. However, the submitter provides the additional information to the Office of Toxic Substances (OTS) by a date acceptable to and specified by OTS.

-2-

CIVIL PENALTIES

Assessment of civil penalties will be appropriate for most violations of a TSCA Section 4 test rule. Specific violations are addressed in the ASSESSMENT OF CIVIL PENALTIES section under the CIRCUMSTANCES subsection.

CRIMINAL SANCTIONS

In some instances, the magnitude of a particular violation or the number of repeat offenses will warrant the use of criminal sanctions under TSCA Section 16 or 18 U.S.C. 2 or 1001.

Several factors distinguish criminal cases from administrative or civil actions. First, criminal sanctions will ordinarily be limited to cases in which the violation is accompanied by evidence of "guilty knowledge" or intent on the part of the responsible party. TSCA imposes criminal penalties only for violations of the Statute which are "knowingly or willfully" committed. For example, criminal prosecution may be appropriate where manufacturer or processor management personnel make a decision to violate the TSCA Section 4 test rule by falsifying data or intentionally concealing data through omission or selective reporting.

ASSESSMENT OF CIVIL PENALTIES

EPA will assess penalties against each manufacturer or processor in violation of a TSCA Section 4 test rule. The following Gravity-Based Civil Penalty (GBP) Matrix will be applied when assessing civil penalties.

GRAVITY-BASED PENALTY MATRIX

Extent of Potential Damage				
Circumstances (probability of damages)	A Major	B Significant	C Minor	
High Range:				
1	\$25,000	17,000	5,000	
2	-			
Mid Range:				
3	15,000	10,000	1,500	
4	10,000	6,000	1,000	
Low Range				
5	5,000	3,000	500	
6	2,000	1,300	200	

-3-

The following general criteria will be applied in making Gravity Based Penalty determinations for violations of TSCA Section 4 test rules.

NATURE

All violations TSCA Section 4 test rules will constitute "hazard assessment" violations, as defined in the TSCA Civil Penalty Policy (45 FR 59771, September 10, 1980).

EXTENT

The TSCA Civil Penalty Policy provides for three measures of the extent of a violation: Major, Significant, and Minor. Extent is used

to take into consideration the degree, range, or scope of the violation. The criteria are generally based upon the disruption to an EPA review due to the increased time to generate acceptable data. The following criteria will apply to this consideration:

- A) Major - Studies requiring at least 90 days to perform. Examples would include two-year bioassays and avian reproduction tests.
- B) Significant - Studies requiring at least 14 but less than 90 days to perform. Examples would include a 21-day Daphnid chronic toxicity test and a 21 to 42 day hen acute delayed neurotoxicity test.
- C) Minor - Studies requiring less than 14 days to perform. Examples would include a 48-hour EC50 Daphnid acute toxicity test and a rat oral LD50 test.

Note: The time periods are the time spent in the laboratory exclusive of the time spent to write reports, analyze data, etc.

CIRCUMSTANCES

The matrix retains five levels of the "Circumstances" axis. The following criteria will apply to this consideration.

- 1) High Range (Level 1) - Violations which seriously impair the Agency's ability to evaluate the hazards of chemicals. Level 1 violations include the following categories:

Level 1

(1) Falsification of submitted data.

(2) Failure to test.

-4-

(3) Failure to complete required testing after making a commitment to conduct testing.

(4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the failure seriously impairs the Agency's ability to evaluate the substance (GLP violations addressed in a separate EPR).

- (5) Failure to submit letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required.
- (6) Submitting a letter of intent to test or a valid request for exemption from testing more than 60 days after the letter of intent to test is required.

2) Middle Range (Levels 3 and 4) - Violations which impair the Agency's ability to evaluate chemicals in an important but less than critical way. Level 3 and 4 violations include the following categories:

Level 3

- (1) Completing a study but submitting it to EPA more than 30 days after the required date without having an EPA written approved modification to the schedule.
- (2) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is impaired in an important but less than critical way.
- (3) Failure to submit study plans or submitting study plans more than 30 days after the required date taking into consideration any extensions approved in writing by EPA.
- (4) Submitting letters of intent to test or submitting a valid request for exemption from testing more than 30 but within 60 days after the letter of intent to test is required.

Level 4

- (1) Failure to submit or submitting interim progress reports more than 30 days after the documents are required.

-5-

3) Low Range (Levels 5 and 6) - Violations which minimally impair the Agency's ability to evaluate the hazards of a chemical. Level 5 and 6 violations include the following categories:

Level 5

- (1) Completing a study and submitting it to EPA more than 15 but within 30 days after the required date but without an EPA written approved modification to the schedule.
- (2) Submitting a letter of intent to test or valid request for exemption from testing more than 15 but within 30 days after the letter of intent to test is required.
- (3) Submitting study plans, interim progress reports or submitting final reports more than 15 but within 30 days after the required date without an EPA written approved modification to the schedule.
- (4) Initiating a study after the date indicated in the approved study plan without an EPA written approved modification to the schedule but the final report is submitted by the required date and accepted by EPA (late initiated studies resulting in late final reports shall be dealt with as late final reports or late study submissions).
- (5) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is minimally impaired.

Level 6

- (1) Categories 1, 2, and 3 described under Level 5 above if submitted not more than 15 days after the required date.

CONTINUING VIOLATIONS

Under section 16 of TSCA, EPA may assess penalties for each day a violation continues. Per day assessments will apply when the gravity of the violation warrants a higher penalty than can be assessed through a single day penalty assessment.

Continuing violations include the following categories described in

the CIRCUMSTANCES subsection of this ERP:

- (1) Falsification of data.
- (2) Failure to test.
- (3) Failure to complete tests after making a commitment to conduct testing.
- (4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in a serious impairment or impairment in an important but less than critical way of the Agency's ability to evaluate the substance.
- (5) Failure to submit or late submissions of letters of intent to test after required date.
- (6) Failure to submit valid requests or submission of invalid requests for exemption from testing after the letter of intent to test is required.

The period of violation should apply from the date the violative action begins to the date EPA grants a modification to the standards or schedule. The number of days for the violation shall be calculated based on the number of days a manufacturer manufactures (imports); or when a processor is required to test, the number of days a processor processes a substance during the entire violative period. When a person both processes and manufactures during the violative period, the number of days shall be based on the greater of the two (either processing or manufacture only when the test rule requires manufacturers and processors to test. If the rule requires only the manufacturer to test, then the violative period is based on the days of manufacture. If a single batch is manufactured or processed in more than one day, each batch shall be calculated as one day in violation, except for continuous operations. Two or more batches manufactured or processed in a single day at the same site shall be calculated as one day in violation.

MULTIPLE VIOLATIONS

Multiple violations will apply to situations where a single manufacturer or processor, or consortium commits to perform more than one test required by a TSCA Section 4 test rule. Each test found with violations shall warrant the assessment of a separate penalty.

Multiple violations include all of the categories described in the CIRCUMSTANCES subsection of this ERP except for certain instances involving failure to submit study plans. A multiple violation situation shall not exist for study plans if they address all required tests under one test rule and are submitted at the same time by one company or consortium.

ADJUSTMENT FACTORS

Once the GBP has been determined, upward and downward adjustments to the penalty amount may be made in consideration of culpability, history of violations, ability to pay, and such other matters as justice may require. EPA will apply these adjustment factors as described in the TSCA Civil Penalty Policy (45 FR 59770, September 10, 1980). Considerations unique to TSCA Section 4 test rules are discussed below.

1. Voluntary Disclosure

Penalty reductions up to 25% will be applied for voluntary disclosure of violations by manufacturers or processors subject to a TSCA Section 4 rule. To be eligible, a manufacturer or processor must make the disclosure prior to being notified of a pending inspection and prior to EPA receiving any information relating to the alleged violation. This reduction may be made in calculating the proposed penalty before issuing a civil complaint. The complaint should state the original penalty, the reduced penalty, and the reason for reduction. All other reductions in the GBP should be made after the complaint is issued.

2. Immediate Voluntary Disclosure

In cases where manufacturers or processors subject to a TSCA Section 4 rule report potential violations to EPA within 30 days of having reason to believe that they may have a violation, additional penalty reductions up to 25% may be applied.

3. Gains from Noncompliance

Noncompliance with a TSCA Section 4 rule may enable a person to accrue significant economic gains, since the responsible party may not expend the necessary funds to properly conduct the required testing or

to conduct the test at all. Gains may also be realized because EPA does not regulate many substances or mixtures until required testing is submitted and evaluated. Therefore, the penalty policy specifies that violations likely to result in economic gain result in level 1 penalty calculations for each day the chemical is manufactured, processed or imported. The extent category for level 1 violations depends on the type of study, i.e., chronic, subchronic, or acute and is therefore relative to the costs for such tests. In settling cases, the Agency should assure that the final penalty is greater than the economic gain.

TSCA SECTION 4 CIVIL PENALTY MATRIX

CIRCUMSTANCES	EXTENT OF POTENTIAL DAMAGE		
	MAJOR	SIGNIFICANT	MINOR
Level 1			
*+ 1) Falsification of submitted data			
*+ 2) Failure to test			
*+ 3) Failure to complete required tests after making commitment to conduct testing			
*+ 4) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is seriously impaired	\$25,000	\$17,000	\$5,000
*+ 5) Failure to submit letter of intent to test or valid request for exemption from testing more than 60 days after the letter of intent to test is required			
*+ 6) Submitting a letter of intent to test more than 60 days after the required date			
*+ 7) Submitting a valid request for exemption more than 60 days after the letter of intent to test is required			
Level 3			
+ 1) Completing a study but failing to submit	\$15,000	\$10,000	\$1,500

it to EPA more than 30 days after the required date without having an approved modification to the schedule

- 2) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is impaired in an important but less than critical way
- + 3) Failure to submit study plans**or submitting study plans more than 30 days after the required date taking into consideration any extensions approved in writing by EPA
- +* 4) Submitting a letter of intent to test more than 30 but within 60 days after the required date
- + 5) Submitting a valid request for exemption from testing more than 30 but within 60 days after the letter of intent to test is required

LEVEL 4

- | | | | |
|--|----------|----------|---------|
| + 1) Failure to submit or submitting interim progress reports more than 30 days after the documents are required | \$10,000 | \$ 6,000 | \$1,000 |
|--|----------|----------|---------|

LEVEL 5

- | | | | |
|--|----------|----------|--------|
| + 1) Completing a study and submitting it to EPA more than 15 days but within 30 days after the required date but without an approved modification to the schedule | | | |
| *+ 2) Submitting a letter of intent to test more than 15 but within 30 days after the required date | \$ 5,000 | \$ 3,000 | \$ 500 |
| + 3) Submitting a valid request for exemption from testing more than 15 but within 30 days after the letter of intent to test is required | | | |
| + 4) Submitting study plans**, interim progress reports or submitting final reports more than 15 days but within 30 days after the required date without an | | | |

EPA written approved modification to the schedule

- 5) Initiating a study after the date indicated in the approved study plan without an EPA written approved modification to the schedule but the final report is submitted by the required date and accepted by EPA
- 6) Failure to adhere to test standards or failure to obtain written EPA approval on modifications to test standards before effecting changes which results in an OTS determination that the Agency's ability to evaluate the substance is minimally impaired

Level 6

+ 1) Same as numbers 1, 2*, 3, or 4 under level 5 violations except submitted within 15 days after the required date	\$ 2,000	\$ 1,300	\$ 200
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* Subject to Continuing Day Assessment

+ Subject to Multiple Violation factor

** A multiple violation situation shall not exist if study plans to address all required tests are submitted at the same time under one test rule by one company or consortium.

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